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Re-evaluation Decision

RVD2012-01

Sodium and Potassium Dimethyldithiocarbamate Salts

(publié aussi en français)

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Re-evaluation Decision

After a re-evaluation of the biocides sodium and potassium dimethyldithiocarbamate salts, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing sodium or potassium dimethyldithiocarbamate salts for sale and use in Canada.

An evaluation of available scientific information found that products containing sodium or potassium dimethyldithiocarbamate salts do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of sodium and potassium dimethyldithiocarbamate salt uses, new risk-reduction measures must be included on the labels of all sodium and potassium dimethyldithiocarbamate products. Additional data are being requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of sodium and potassium dimethyldithiocarbamate salts was first presented in Proposed Re-evaluation Decision document PRVD2011-05, *Sodium and Potassium Dimethyldithiocarbamate Salts*, a consultation document.¹ This Re-evaluation Decision document² describes this stage of the PMRA's regulatory process for the re-evaluation of sodium and potassium dimethyldithiocarbamate salts as well as summarizes the Agency's decision and the reasons for it. Comments received during the consultation process did not result in substantial changes to the proposed regulatory decision as described in the PRVD, and Appendix I summarizes the comments and provides the PMRA's response. A scientific rationale was provided by the registrant in lieu of air monitoring data requested in the PRVD under section 19 of the *Pest Control Products Act*. A summary of this scientific rationale and the PMRA's response to it are provided in Appendix II. This decision is consistent with the proposed re-evaluation decision stated in PRVD2011-05. To comply with this decision, registrants of products containing sodium or potassium dimethyldithiocarbamate salts will be informed of the specific requirements affecting their product registrations.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Sodium and potassium dimethyldithiocarbamate salts have been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of sodium and potassium dimethyldithiocarbamate salts. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

The USEPA re-evaluated sodium and potassium dimethyldithiocarbamate salts and published its conclusions in a 2009 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2011-05, *Sodium and Potassium Dimethyldithiocarbamate Salts*.

What Are Sodium and Potassium Dimethyldithiocarbamate Salts?

Sodium and potassium dimethyldithiocarbamate salts are biocides registered in Canada for use in industrial fluids including air washing systems, cooling water systems, petroleum secondary and tertiary recovery water, drilling muds/completion fluids/packer fluids/drilling fluids and pulp and paper mills. They are also used in metal working fluids. In addition, potassium dimethyldithiocarbamate is used for preservation of paper making additives, crude oil/diesel/distillate heating oil (during storage) and brine solution (leather industry), while sodium dimethyldithiocarbamate is used for preservation of paste (starch and casein). Since a product containing sodium dimethyldithiocarbamate was cancelled by the end-use registrant, the following uses are not included in the RVD: cotton fabric, paper and paper board, and alginate paste.

Health Considerations

Can Approved Uses of Sodium and Potassium Dimethyldithiocarbamate Salts Affect Human Health?

Sodium and potassium dimethyldithiocarbamate salts are unlikely to affect your health when used according to the revised label directions.

People could be exposed to sodium and potassium dimethyldithiocarbamate salts through consumption of food that has come in contact with treated paper products or by wearing/contacting treated leather products. In addition, occupational exposure of workers involved in various industrial processes may occur. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human populations (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Sodium and potassium dimethyldithiocarbamate salts are unlikely to adversely affect human health provided that risk-reduction measures are implemented. Additional mitigation measures are required by the PMRA to further protect the Canadian population.

Environmental Considerations

What Happens When Sodium and Potassium Dimethyldithiocarbamate Salts Are Introduced into the Environment?

Sodium and potassium dimethyldithiocarbamate salts are unlikely to affect non-target organisms when used according to the revised label directions.

Sodium and potassium dimethyldithiocarbamate salts are unlikely to pose an adverse effect to the environment if used according to the revised labels. The PMRA requires additional label statements regarding environmental hazard and prohibiting effluent discharge into the environment.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of sodium and potassium dimethyldithiocarbamate salts, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional hazard label statements
- Additional personal protective equipment for workers
- A label statement limiting the use of sodium and potassium dimethyldithiocarbamate salts to non-food contact materials and products

Environment

- Additional label statements regarding environmental hazard and prohibiting effluent discharge into the environment.

Appendix III lists all required label amendments.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under sections 12 of the *Pest Control Products Act*. The registrants of sodium and potassium dimethyldithiocarbamate salts must provide these data or an acceptable scientific rationale to the PMRA within the time line specified in the decision letter. Appendix IV lists all data requirements.

Other Information

Any person may file a notice of objection³ regarding this decision on sodium and potassium dimethyldithiocarbamate salts within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision), or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

³ As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comment pertaining to the use pattern description

The registrant submitted a clarification of the use pattern, stating that the use in “crude oil/distillate heating oil (during storage)” was a use specific to potassium dimethyldithiocarbamate only.

PMRA Response

The PMRA agrees with the clarification, and this has been incorporated into this document.

Appendix II Submitted Section 19 Data and Response

In lieu of providing air monitoring data required under section 19 of the *Pest Control Products Act* as outlined in PRVD2011-05, *Sodium and Potassium Dimethyldithiocarbamate Salts*, the registrant requested a waiver.

PMRA Response

The risk assessment and mitigation measures described in PRVD2011-05, *Sodium and Potassium Dimethyldithiocarbamate Salts*, are expected to be conservative and protective of any risk associated with exposure to the degradates. Dimethyldithiocarbamate salts are more prone to hydrolysis and degradation in acidic conditions. As the pH of metalworking fluids and brine solutions ranges from 7 to 10.5, the formation of dimethylamine and carbon disulfide in these fluids is expected to be reduced. In addition, engineering controls and personal protective equipment are effective in reducing worker exposure to metal working fluids and brine solutions. As such, exposure to carbon disulfide and/or dimethylamine from the use of sodium and/or potassium dimethyldithiocarbamate salts for metalworking fluid and/or brine solutions is not expected to be of concern.

The PMRA accepts the registrant's request to waive the data required under section 19 of the *Pest Control Products Act*.

Appendix III Revised Label Amendments for Products Containing Sodium and Potassium Dimethyldithiocarbamate Salts

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of products containing sodium or potassium dimethyldithiocarbamate salts in Canada must be amended to include the following statements to further protect workers and the environment.

- I) For the technical grade and end-use products containing potassium dimethyldithiocarbamate, the following must be included on the primary panel of the label:

WARNING
POISON
CORROSIVE TO EYES
SKIN IRRITANT
POTENTIAL SKIN SENSITIZER

- II) For the technical grade and end-use products containing potassium dimethyldithiocarbamate, the following statements must be included in the section entitled **PRECAUTIONS**:

Corrosive to the eye. DO NOT get in eyes.
Corrosive to skin. DO NOT get on skin.
Potential skin sensitizer
Harmful if swallowed

- III) For the technical grade, manufacturing and end-use products containing sodium dimethyldithiocarbamate, the following must be included on the primary panel of the label:

DANGER
CORROSIVE TO EYES
POISON
SKIN IRRITANT

- IV) For the technical grade, manufacturing and end-use products containing sodium dimethyldithiocarbamate, the following statements must be included in the section entitled **PRECAUTIONS**:

Harmful if swallowed.
CORROSIVE to the eye. DO NOT get in eyes.
May irritate the skin. Avoid contact with skin.

- V) For all end-use products containing sodium or potassium dimethyldithiocarbamate salts, the following statement must be included in the section entitled **PRECAUTIONS**:

Wear long-sleeved shirt, long pants, chemical-resistant gloves, protective eyewear (goggles or face shield) when handling the product, clean-up and repair activities.

- VI) For potassium dimethyldithiocarbamate use for preservation of the brine solution, the following statement must be included in the section entitled **PRECAUTIONS**, immediately following the personal protective equipment requirement described in (V) above:

In addition, wear long chemical-resistant gloves, an impermeable apron and rubber safety boots when removing cured hides/skins from the brine raceway.

- VII) For products having uses in paper/paperboard manufacturing processes, the following statement must be included in the section entitled **DIRECTIONS FOR USE**:

DO NOT use to treat paper or paperboard which will contact food.

- VIII) For all sodium and potassium dimethyldithiocarbamate salts end-use products, the following statement must be included in the section entitled **ENVIRONMENTAL HAZARDS**:

Toxic to aquatic organisms.

- IX) For all sodium and potassium dimethyldithiocarbamate salts end-use products, the following statements must be included in the section entitled **DIRECTIONS FOR USE**:

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.
DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Appendix IV Additional Data Requirements

The following data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to the registrant by the PMRA.

To support the continued registration of the technical grade sodium and potassium dimethyldithiocarbamate salts, the following data are required:

DACO 4.4.4 Combined Chronic/Oncogenicity study (rat and mouse)

DACO 4.5.1 Multigeneration Reproduction (rat)

These studies must be conducted with the registered technical grade active ingredient, or a product with equivalent formulation and guarantee, and be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances or Organisation for Economic Co-operation and Development guidelines.